

### ***Remarks***

Reconsideration of this Application is respectfully requested.

Claims 1-3 and 5-10 are pending in the application, with claims 1, 5 and 8 being independent claims. Claim 4 was cancelled in the amendment filed August 27, 2004. New dependent claims 11-13 are sought to be added.

The Applicant thanks Examiner Michael Mendoza and Primary Examiner Glenn Dawson for the courtesy extended to the Applicant's representatives Peter Tung and Mary Tung during an interview regarding the instant application on July 12, 2004.

Based on the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding rejections and that they be withdrawn.

### ***Rejection of Claims under 35 U.S.C. 103(a)***

The Examiner has maintained the rejection of claims 1-3 as being unpatentable over Rudolph (US Patent No. 5,265,595) "in view of Dyrud et al." (U.S. Patent No. 5,819,731). The Examiner maintains that Rudolph teaches a mask having an improved means for being secured over the nose and the mouth of a patient, the improvement comprising: a pair of elastic bands, both ends of the each pair affixed at points of attachment to each of both sides of the mask, adjustably securable to the patient by pulling the ends anteriorly through the points of attachment, and wherein the elastic bands are affixed at four separate points on the mask. Rudolph fails to teach wherein the bands are extendible to loop over and around each ear of the patient.

The Examiner maintains that Dyrud et al. teaches a mask with common strap for looping around the ear of the patient for securing a mask. The Examiner continues to argue that it would

have been obvious to one of ordinary skill in the art to modify the mask of Rudolph to include the strap of Dyrud *et al.* to prevent entanglement of the wearer's hair or otherwise ruin the wearer's hair style. Regarding the limitations of claim 3, the Examiner states that "Rudolph/Dyrud teach wherein the elastic bands are affixed at two separate points on the mask (34 or 36)."

Applicant respectfully disagrees. There is no motivation to combine the teaching of Rudolph in view of Dyrud. While the Examiner provides the motivation of preventing entanglement of the wearer's hair or otherwise ruin the wearer's hair style, this is a throw away basis for combining the two inventions as Rudolph teaches a mask that requires a skull cap and straps to sealably secure the mask to the wearer's head (col. 3, lines 11-15). The mask of Rudolph requires a firm mask fit and facial seal. While comfort of fit is desired, no mention of the importance of the wearer's appearance is mentioned as being relevant. There would be no motivation to combine a teaching which is based upon the wearer's appearance when the Rudolph mask requires assuring a tight seal as the primary purpose of the attaching straps.

Additionally, *in arguendo*, assuming one is motivated to combine the teachings of Rudolph in view of Dyrud, no reasonable expectation of success has been provided. With the substitution of the skull cap for straps that fit over the ears, as suggested by Dyrud, one of ordinary skill in the art would not expect such a device to function for the purpose intended by Rudolph, i.e. such straps would not allow sealably securing the mask of Rudolph and allowing its proper use. Thus one of ordinary skill in the art would not combine the two inventions. Similarly, the mask of Rudolph would not function using the modification of Dyrud; there is no reasonable expectation that the straps taught by Dyrud would be able to sealably secure the mask of Rudolph.

The combination of the teaching of Rudolph in view of Dyrud further does not anticipate the instant claims. Nowhere in the individual and combined teachings of Rudolph in view of Dyrud is there a teaching of pulling the strap *anteriorly through* points of attachment on the mask. In the teaching of Rudolph, while the strap fasteners (12) may be pulled anteriorly to secure the mask, the straps are not pulled through the points of attachment (See Fig. 1 and Fig. 9) but are rather pulled so that they can be secured to posts (121) located on the mask. Furthermore, due to the way the securement strap (11) of the mask are fitted through the strap receiving aperture (163) of the strap fastener (12), securing the mask by pulling the straps anteriorly is not possible. Additionally, the strap fastener is not a physical part of the mask as are the attachment posts. In the teaching of Dyrud, a strap is secured by adjustments of an ear loop attachment with a drop down feature. Adjustment and donning of the mask is by sliding through the mask's orifices. The design of the mask does not allow pulling the bands anteriorly to secure the mask.

Structurally, the teachings of Rudolph in view of Dyrud do not anticipate the instant claims. Rudolph teaches four separate straps, not a pair for attaching the mask to the wearer. Dyrud does not teach a pair of bands for securing a mask but rather a single band. This band may be of separate sections but they tie or clip together, which is not that of the instant claims.

In a combination teaching as described by the Examiner, a pair of bands is used to attach the Rudolph mask. However, neither patent teaches using a pair of bands to attach a mask. There is no teaching in either of the patents that suggests using a pair of bands to attach a mask to a wearer. Applicants respectfully argue that the only way the Examiner could arrive at the instant invention based upon the teachings of Rudolph in view of Dyrud is hindsight reconstruction of the Applicant's invention. While any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning (M.P.E.P. 707.07), it cannot "include knowledge

gleaned only from the applicant's disclosure." The Examiner has not provided any basis for why the combination of the two teachings would result in an oxygen mask with *two* bands for attaching to the wearer when neither cited patents even remotely suggests using two bands for attachment.

M.P.E.P. § 2143 states the three basic criteria that must be met for obviousness. "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." [Emphasis added by Applicant]

To further argue that the Examiner is using hindsight reconstruction of the Applicant's claims, it is pointed out that the invention of Dyrud has a drop down feature which necessitates the band go behind the wearer's neck (Figs. 1 & 2). If the Examiner is only relying upon Rudolph in view of Dyrud to anticipate the instant invention and not also using Applicant's disclosure, a mask based upon the combination of the two references would be expected to have a band that goes behind the wearer's neck, allowing for the drop down feature taught by Dyrud. In the rejection, the Examiner only provides a mask that has ear loops for attachment. While Dyrud has ear loops for attaching a mask, Dyrud provides no teaching on providing ear loops without also a drop down feature where the band goes behind the wearer's neck. The Examiner

has separated this feature from Dyrud's teaching of ear loops with a drop down feature to hindsight anticipate the Applicant's claims.

Therefore, the Applicant maintains that without the guidance of the Applicant's specification, the Examiner could not have arrived at the Applicant's invention using Rudolph and Dyrud. Applicant maintains that the obviousness rejection made by the Examiner is merely hindsight reconstruction based upon the Applicant's disclosure.

It is further argued by the Applicant that the invention of the instant claims is directed to an *oxygen delivery mask*. Neither of the patents (US Patent No. 5,265,595 and U.S. Patent No. 5,819,731) cited by the Examiner in the obviousness rejection teaches or suggests an oxygen delivery mask. Applicant argues that the art cited is entirely deficient in this regard.

The Applicant further argues that the Examiner's statement that the term "oxygen mask" is not given patentable weight due to its presence in the preamble of the claims is not proper. With regard to Claim 1, the Court of Appeals of the Federal Circuit has determined that a recitation in the preamble must be given patentable weight, if the claim is written in a Jepson format (*Rowe v. Dror*, Fed. Cir. 09-1304 (1997)).

The count, which corresponds to claims 53-66 of the Rowe application and claims 1-8, 10-15 and 17-21 of the Dror patent, reads:

1. In a balloon angioplasty catheter of the type comprising a catheter body and a balloon positioned along the length of the catheter body, said balloon including means for remotely inflating and deflating said balloon; the improvement comprising: ...

Inspection of the entire record in this case reveals that "angioplasty" is, in fact, a structural limitation of Rowe's claims. To begin with, the form of the claim itself, the so-called "Jepson" form, suggests the structural importance of the recitations found in the preamble. The Jepson form allows a patentee to use the preamble to recite "elements or steps of the claimed invention which are conventional or known." 37 C.F.R. 1.75(e) (1996). When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope.

See Pentec, Inc. v. Graphic Controls, Corp., 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985) ("Although a preamble is impliedly admitted to be prior art when a Jepson claim is used, . . . the claimed invention consists of the preamble in combination with the improvement.") (citations omitted); United States Patent and Trademark Office, Manual of Patent Examining Procedure § 608.01(m) (6th ed. rev. Sept. 1995) ("[The Jepson form of claim] is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination."). Thus, the form of the claim itself indicates Rowe's intention to use the preamble to define, in part, the structural elements of his claimed invention. The device for which the patent claims "an improvement" is a "balloon angioplasty catheter."

Similarly, it is maintained by the Applicant that the device for which the Applicant claims "an improvement" is an "oxygen mask." Furthermore, in the Interview Summary mailed as part of the November 7, 2003 Office Action, the Examiner stated "bring an 'oxygen mask' out of the preamble and into the structural limitations of the claim." The examiner has not yet addressed the placement of the "oxygen mask" limitations into claims 5 and 8. In the Interview conducted on July 12, 2004, the Examiner stated that he does not believe that there are any structural recitations in the claims. The Applicants disagree for the reasons set forth herein, namely, that "oxygen mask" intrinsically comprises a set of structural characteristics in which a cloth mask or a gas monitoring mask would not contain.

The mask taught by U.S. Patent No. 5,819,731 is not an oxygen delivery mask. The mask taught by US Patent No. 5,265,595 is for measuring respiration and metabolism and is designed to have minimum dead space and to be as airtight as possible. As such, it is entirely unsuitable for use as an oxygen delivery mask. It is recognized in the art that an oxygen delivery mask requires the ability to have ambient air to intermix with the oxygen being delivered to the wearer of the mask. Decreasing dead volume and making the mask airtight would not allow this to occur. Additionally, carbon dioxide exhaled by the patient would build up in an airtight mask

and could lead to a potentially fatal response in some patients with certain respiratory conditions, such as obstructive pulmonary disease.

Based upon the preceding arguments, applicant therefore requests that the rejection of claims 1-3 under 35 U.S.C. 103(a) be withdrawn.

***Finality of Previous Office Action***

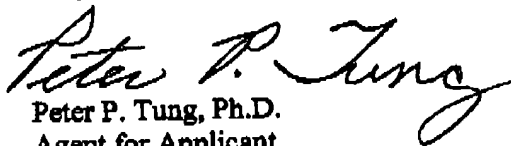
Applicant respectfully requests withdrawal of the finality of the previous Office Action, dated April 19, 2004. According to the MPEP § 706.07(a), "second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement ..." The Applicant asserts that the explanation that "any mask capable of allowing a person to breathe oxygen can be considered an oxygen mask" has never been stated in any Office Action and represents a new grounds for rejection. Accordingly, it is improper for the Examiner to make the previous Office action final. Applicant therefore respectfully requests that the Examiner withdraw the finality of the April 19, 2004 Office Action.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,



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